

State of Rhode Island
Department of Health
Board of Medical Licensure & Discipline



IN THE MATTER OF:
Boris Bergus, MD
License No.: MD 07797
Case Nos.: 21-1528 A

SUMMARY SUSPENSION

The Rhode Island Board of Medical Licensure and Discipline ("Board") has reviewed and investigated the above-referenced complaint regarding Dr. Boris Bergus (respondent).

FINDINGS OF FACT

1. Respondent graduated from Harvard Medical School in 1988, his physician license in Rhode Island was issued July 3rd, 1990. He does not report a specialty.
2. Respondent lists his place of business at America's Vein Center in East Greenwich and in Lincoln.
3. In response to a previous complaint (C201186) regarding Respondent's storage and use of expired medications, the Board did an announced inspection on 8/28/2020 and found there were no expired medications or deficiencies.
4. The Board received an anonymous complaint regarding Respondent on 11/5/2021, which stated

"PLEASE DO NOT TELL HIM YOU ARE VISITING. HE WILL HIDE EVERYTHING IN HIS OFFICE!!!! In both of his offices, Dr. Boris Bergus carries expired solutions. He also injects old solutions that he mixes with Botox, that expired in 2012. He also changed his company names 3 times in 2020 in order to collect the PPE loan and never once gave the workers a covid relief bonus. He has a medical assistant who is acting as a ultrasound tech. who has no certification. Also medical assistants insert IVs. On your site it clearly states medical assistants ARE NOT allowed to do that. Insurance carriers have banned him for being a fraud. He uses Dr. Kaleed Yehia's name for all billing purposes. Go into his office UNSUSPECTLY and you will see what I am talking about. All of his cosmetic machines are made from Korea Alibaba". His fillers are purchased through Alibaba which are \$20 per unit when regular fillers (like Restalyne) are \$400. HE WILL CHARGE PTS 650\$ for 20\$ filler he bought from alibaba ! Please visit without him knowing. Only way he will get caught !

5. The Investigative Committee of the Board met on November 17th, 2021 and reviewed the instant complaint. The committee ordered the investigators to conduct an unannounced in person inspection of both offices to investigate the above referenced matter.

6. On December 2, 2021 two investigative teams (Team A to inspect Lincoln Site, Team B to inspect East Greenwich site) were dispatched to the East Greenwich Site and the Lincoln site to conduct unannounced inspections. Each team included a Board representative and RIDOH pharmacy representative. The teams arrived at noon, a time which based on previous experience was least disruptive to the office.

7. Team A went to the Lincoln Site and conducted an unannounced inspection, upon arrival introduced themselves to Respondent and his assistant. The Board investigator reported:

"Upon entering the building, we were introduced to Dr. Boris Bergus and an assistant/manager. Dr Bergus was with us the entire time we conducted the inspection of the rooms. Dr. Bergus took us to the conference room in the back right corner of suite. This was a large room with a divider to separate the as there was a conference table in one section and Fridge and storage in the other side of room. Dr. Bergus was given a copy of the complaint and explained we are here to conduct an inspection. Dr Bergus stated that we usually get notified of inspections. I told him that this one was to be conducted as an unannounced inspection."

8. Team A noted several very serious findings that corroborated the complaint. In the refrigerator used for drug storage Team A noted:

- a) The vast majority of medications reviewed were expired;
- b) Two bags of Lactated Ringers Intravenous solution with unreadable writing (this is considered a mislabeled drug);
- c) In the refrigerator door was an open box of Botox from injection from Korea (Botilax 100) which contained a hypodermic needle sticking out of it open to the air- this is a dangerous practice as the open needle is a portal for bacteria, fungi or other airborne contamination. This was a multidose vial with no "beyond use" date marked on it; and
- d) An open box of Botox 100 Allergan units with valid expiration dates 4/2024. This vial had a hypodermic needle sticking out of the top of it, and no dates of being opened marked on the vial.

9. Team A noted the following in Exam Room #7:

- a) 5 unopen vials and one vial of Ketalar (Ketamine Hydrochloride Injection, USP) 500mg per 10ml (50mg/ml) Rx only NDC42023-114-10. Lot 310008, EXP 7/2015 on vials. *(this is an immediate danger to the public since they are expired and Ketamine is a controlled substance, Schedule III and used as a dissociative anesthesia and since it can be used for recreational usage can be diverted)*
- b) 6 unopened vials and two open vials of Ketamine Hydrochloride Injection, USP 500mg per 10ml (50mg/ml) Rx only NDC409-2053-10. Lot 72050DD, EXP Dec 1, 2018 on vials. *(this is an immediate danger to the public and Ketamine is a controlled substance, Schedule III and used as a dissociative anesthesia and since it can be used for recreational usage can be diverted)*
- c) 18 vials of Gentamicin Injection, USP 80 mg/2ml, lot 6109964 EXP. 07/2016. *(this is an immediate danger to the public since this is expired)*
- d) 2 Vials of Haloperidol Injection, USP, 5mg per ml, 1 ML Single dose, LOT M701863, EXP02/2019. *(this is an immediate danger to the public since this is expired)*
- e) Vial Solu-Medrol, NDC00090039-30, 1ml act-O-vil, Methylprednisolone sodium succinate for injection, USP, 40mg per vial, Lot J84841, EXP06/2016. *(this is an immediate danger to the public since this is expired)*
- f) Methylene Blue Injection, USP 1% (10 mg/ml) for slow IV Administration, 10ml single dose vial, NDC17478-504-10, Lot 121402, EXP 12/2014. *(this is an immediate danger to the public since this is expired)*
- g) Seven Vials in box of Diphenhydramine HCl Injection, USP, 50mg/ml High Potency, for deep intramuscular or slow intravenous use, 25X1ml vials. Lot 025350, EXP. 02/2017. *(this is an immediate danger to the public since this is expired)*
- h) Several Packages 3-0 SL-5628 2 metric polysorb braided lactomer 9-1, with EXP dates. 11/2012, 1/2009. *(this is an immediate danger to the public since this is expired)*

- i) 3 dozen box 2-0 3 metric Biosyn, Monofilament Glycomer 30" 75cm, Mfg. date 10-2009, EXP. 10-2014. *(this is an immediate danger to the public since this is expired)*

10. Team A inspected a storage room and found the following:

- a) several boxes of 25 vials of 2% Lidocaine HCl Injection 1000mg/50ml expired as of December 1, 2021.
- b) 3 boxes of 25 vials of Bacteriostatic 0.9% Sodium Chloride Injections all expired with date Dec 1, 2014, Nov 1, 2015. *(this is an immediate danger since it is expired)*
- c) Three boxes of Epinephrine Injection 1mg/ml with an expiration date of Dec 2015. *(this is an immediate danger since it is expired)*
- d) In a small box there was three vials of Liporase which was the only item written in English on the bottle numbers that appeared to be and expiration date of Jan 27, 2024. Dr. stated it was a filler dissolver.
- e) A bottle of Naloxone HCl Injection .4mg/ml with a good expiration date Jan 1, located in this box on the shelf with the Liporase.
- f) A bottle of Acetaminophen 325 mg 100 tablets, with an expiration date of 6/2018 was on the shelf. (expired drug)

11. Team A investigated Exam room 1 and found the following:

- a) Located in a drawer was a bottle of Lidocaine HCl 2% Injections 1000mg/50ml(20mg/ml) LOT 12-081-DK, with an expiration date of Dec 1 2021, which was open.
- b) 3 Bottle of Bacteriostatic 0.9 % Sodium Chloride Lot 24-212-DK with expiration date of Dec 1, 2014. *(this is an immediate danger since these are expired drugs)*
- c) There were 11 black plunger syringes filled with fluid and no labels in a plastic pan. *(this is an immediate danger since these are unlabeled medications)*
- d) There were 10 orange plunger syringes filled with fluid and no labels in a plastic pan. *(this is an immediate danger since these are unlabeled medications)*
- e) There was a box of McKesson Syringe 3cc Lot 15D07C8 all expired 4/2020.

12. Team A inspected Exam Room 3 and found the following:

- a) A prescription bottle of Lidocaine 5% cream for Patient A (alias) Providence, RI. RXXXX. Which was filled from Westchester Compounding Pharmacy, 274 White Pans Rd. Eastchester, NY.
- b) A bottle from Westchester Pharmacy Unreadable type of acid 10%, with an expiration date of 10/27/2021. *(this is a misbranded drug)*
- c) A bottle of Trichloroacetic Acid 20%, Lot 09272021@64, expiration date of 09/27/2021.
- d) McKesson hypodermic Syringe 5cc, lot 5A05048 expiration date of 01/2020.
- e) Facial steamer Model ME I-2001A.
- f) High Frequency Equipment RU-102
- g) Nubway Model Hi-Skin I
- h) Expired needling caps used on machine expiration date of 6/2019.

13. Team A inspected Exam Room 6 and found the following:

- a) *On prepared table* 50ml vial of Lidocaine HCl 2% Injection, usp 1000mg/50ml(20mg/ml) lot11-391DK, Exp. Nov. 1, 2021 (this is an immediate danger since it is an expired medicine)
- b) McKesson Hypodermic Needles 18GX1" Lot 14M1oG8852, EXP. 09/2019.
- c) Box of needles Lot 6301646, exp, 10-31-2021.
- d) Hypodermic Needle 25GX1 ½"-0.5X38mm, ster2015-4, EXP3/2020
- e) 2 50ml vial of Lidocaine HCl 2% Injection, usp 1000mg/50ml(20mg/ml) lot11-391DK, Exp. Nov. 1, 2021. (this is an immediate danger since it is an expired medicine)
- f) Fougera Lidocaine Ointment USP, 5%, RX only tube, EXP. Oct. 2016.
- g) Vial 30ml Multi Dose Bacteriostatic 0.9% Sodium Chloride Injections, LOT 24-212-DK, EXP. Dec 1, 2014. (this is an immediate danger since it is an expired medicine)
- h) Box of Needles lot 6301646, Exp 10-31-2021

14. Team A inspected the remainder of the office and found the following:

- a) 2 boxes Ventolin HFA, Albuterol sulfate Inhalation Aerosol, 18 g, Lot 8ZP8889, EXP 7/2009. (*an immediate danger since expired drug, rescue inhaler for patient with respiratory distress*)
- b) EpiPen Auto injector 0.3mg, Lot. 0GH383, EXP. Jan 2012. (*immediate danger as expired drug loss of potency and infection risk and used to treat life threatening anaphylaxis*)
- c) 2 vials Prochlorperazine, Edisylate Injection, USP 10 mg/2ml, NDC 0641-0491-12, Lot. 098094, EXP 3/2010.
- d) 2 bags of 0.9% Sodium Chloride Injection 500ML, EXP. Aug. 2008
- e) 5 unopened Vials Diphenhydramine, HCl Injectable, USP, 50mg/ml, High Potency 1 ml Dosette Vial, Lot 068076, EXP. 6/2010. (*immediate danger expired drug used to treat allergic reaction and loss of potency*)
- f) Oxygen bottle 25 CU Feet Lot 6W00T192A Exp. 7/11/2011.
- g) McKesson Hypodermic 3 cc Syringes W/O needles, Lot 130907K, EXP 8/2018
- h) Box McKesson Hypodermic 3 cc Syringes W/O needles, Lot 15D07C8, EXP 4/2020
- i) Box 18 GX1 ½ Needles, Lot PA1726, EXP 12/2016
- j) Numerous bags of instruments in Sterile bags sealed with no dates.
- k) Numerous bags of expired products.

Expired items locate on prep table in room 7

- a) 22 unopened and 1 Open, vials of 30 ml Multi-does Bacteriostatic, 0.9% Sodium Chloride Injection USP, Lot 50-257-DK, EXP Feb 1, 2017.
- b) 1 unopened and 2 open vials of Epinephrine Injection, USP, 1:1000 (1 mg/ml), Muti does vial 30ml, DT0S0G5, EXP. June 2017.
- c) 2 vials 30 ml, Lidocaine HCl 2% and Epinephrine 1:1000, Injection, USP, For infiltration and nerve block. Not for Epidural or caudal use, Lot 22-508-DK, EXP Jan 1, 2014.
- d) 2 Vials Gentamicin, 80 mg/2ml, NDC63323-010-02, Lot. 6109664, EXP 5/2016.
- e) Sheet on prep table of mixing ratios.

Expired items in Room 7 Shelve

- a) Vial of Epinephrine Injection, USP, 1:1000 (1 mg/ml), Muti does vial 30ml, DT087J5, EXP. 9/2017.
- b) Lidocaine HCl 2% and Epinephrine 1:1000, Injection, USP, For infiltration and nerve block. Not for Epidural or caudal use, Lot 22-508-DK, EXP Jan 1, 2014.
- c) Liporase which was the only item written in English on the bottle numbers that appeared to be and expiration date of Jan 27, 2024.
- d) Box containing 4 unopened vials of Methylene Blue Injection, USP 1% (0 mg/ml) for Slow IV Administration. Lot 121402, EXP 12/2014.
- e) Direction on door IV Set up.
- f) End of Day instruction for Staff.
- g) Restalyne/Radiess Set up instruction.
- h) Set up instructions for Retics and Set up for Visuals.
- i) BD Vacutainer SST, REF 367988, 100 tubes, Blood collection tubes, Lot 7074740, EXP 3-31-2018.
- j) BD Vacutainer SST, REF 367987, 100 tubes, Blood collection tubes, Lot 4024677, EXP 1-2015.

Patient room 8 had the following expired items.

On table

- a) CO2 Laser Machine, Quanta 1470-1470nm
- b) Thermal Life Machine 1470
- c) Nitro-Bid (Nitroglycerin Ointment USP, 2%) Net t 30 Grams, EXP. Oct 2020
- d) Open Vial 50ml vial of Lidocaine HCl 2% Injection, usp 1000mg/50ml(20mg/ml) lot 12-081-DK, Exp. Dec. 1, 2021.

Expired items on Storage Shelf Rack in room 8 items

- a) 2 open vials 50ml vial of Lidocaine HCl 2% Injection, usp 1000mg/50ml(20mg/ml) lot 12-081-DK, Exp. Dec. 1, 2021.
- b) Claps in sterilized bags, no dates of be sterilization.
- c) 2 boxes of Xinda Surgical Blades, Lot 201301, EXP 1/2018
- d) Multiple bags of medical instruments in Sterilization bags. Some with dates and initials some with no information.
- e) Polysurge 1470nm-30W

Inspection of Patient room 9 had the following expired items.

- a) Open Bottle of Ketamine with an expired date.
- b) Open IV bag Partially used.

15. Dr. Bergus was provided a copy of the inspection questions form by the inspector.

16. Team B conducted an unannounced inspection of the East Greenwich site, introduced themselves to the receptionist, and explained the reason for the inspection. The receptionist was provided with a copy of the complaint. She left the room to locate a physician. Upon her return she stated there was no doctor available but allowed Team B into the facility to conduct the inspection.

17. Team B made the following findings:

In the medication supply room (the last door on the right, down a hallway and across from one of the procedure rooms):

- a) approximately 250 bottles of 2% Lidocaine HCL with expiration date of 12/01/2021
- b) an intravenous catheter that expired 5/2015
- c) approximately 30 bottles of Bacteriostatic 0.9% NaCl 30 ml, Lot 11-203-DK with expiration date of Nov. 1, 2013
- d) Epinephrine 30 ml multidose vial, Stock No 9061 Expiration date 12/15
- e) Multiple Sterile Water in injectable bottles Exp. 1 Aug 2017
- f) Lidocaine HCL 2% and Epinephrine Lot 36-320-DK Exp 1 Mar 2015.
- g) HurriCaine Topical Anesthetic GEL Exp. Date 04/2014

- h) Orange post-it note with "Besse Medical Cheap 1-800-543-2111" written on it and attached to a box of 2 gram vials of cefotaxime which expired 06/2015
- i) In the exam room 099% Sodium Chloride bottle with Expiration date of 1 Sept. 2016
- j) Bottles with label handwritten lidocaine made 4/30/2021
- k) In the same exam room Lidocaine HCL 2% multidose bottle was not dated with date opened
- l) In another exam room Bacteriostatic .9% NAACL had an expiration date of Dec 1, 2014
- m) In the same exam room Lidocaine HCL 2% multidose bottle was not dated with the date opened

The following items were observed in the refrigerator:

- a) Syringe Labeled Liporase Mixed on 7/13/21
- b) Povidone Iodine 1% labeled Retics Exp 10/16 on the IV bag
- c) 10% calcium injection Exp. 8/1/2020
- d) Povidone Iodine 5% injection stating on it discard 11/7/2014
- e) No current refrigerator logs. Last written temperature of the refrigerator was 8/28/2020 (date of my last office inspection – which was not unannounced)

- 18. Both pharmacy inspectors noted that these expired medications were in patient use areas.
- 19. Outdated or expired medications lose potency and therefore lack expected efficacy; some of the medications referenced above are used to treat life threatening complications
- 20. Outdated or expired medications are known to be at higher risk for contamination from bacteria, fungi or other organisms; injecting patients with expired medications subcutaneously, intramuscularly or intravenously may cause serious and life-threatening infections.
- 21. The wide distribution of outdated, expired, and/or mislabeled medications throughout the clinical treatment areas utilized by respondent supports the conclusion that these medications are in use, or easily could be used intentionally or inadvertently, in the treatment of patients.

22. The conditions reported above present an immediate danger to the health and safety of patients., It is the opinion of the Medical Director of RIDOH, based upon review of the investigative materials outlined above and to a reasonable degree of medical certainty that the continued practice of medicine of the Respondent presents an immediate danger to the public.

23. Respondent is in violation of Rhode Island General Law § 5-37-5.1 (19):

“Incompetent, negligent, or willful misconduct in the practice of medicine, which includes the rendering of medically unnecessary services, and any departure from, or the failure to conform to, the minimal standards of acceptable and prevailing medical practice in his or her area of expertise as is determined by the board. The board does not need to establish actual injury to the patient in order to adjudge a physician or limited registrant guilty of the unacceptable medical practice in this subsection.”;

ORDER

After considering the above findings, the Director of the Department of Health has determined that the continuation of the practice of medicine by the Respondent would constitute an immediate danger to the public, and the public health, safety and welfare imperatively requires emergency action. It is accordingly ordered that:

1. Respondent is hereby suspended from practicing medicine until further Order of the Department of Health or Board of Medical Licensure and Discipline.
2. Respondent is required to arrange continuity of care for existing patients including ready access to applicable medical records as patients seek transfer of care.

3. Respondent is entitled to an administrative hearing on this suspension in accordance with Rhode Island General Laws §§ 42-35-14 (c), 5-37-8 and 21-28-3.05.

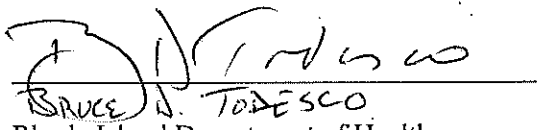
Signed this day 9th December, 2021,



Nicole Alexander-Scott, MD, MPH
Director
Rhode Island Department of Health
3 Capitol Hill, Room 401
Providence, RI 02908

CERTIFICATION

I hereby certify that the Summary Suspension was transmitted via email to Respondent on December 9, 2021. A copy of this Summary Suspension was also transmitted to a Rhode Island constable for personal service upon Respondent.



Bruce A. Todisco
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